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**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	DI-5654
First Inventor	Scott A. Ruddell
Title	Peritoneal Dialysis Catheters
Express Mail Label No.	EK977969705US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages **33**]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets **6**]
5. Oath or Declaration [Total Pages **3**]
 - a. ☒ Newly executed (original or copy)
Copy from a prior application (37 CFR 1.63 (d))
(for continuation/divisional with Box 17 completed)
 - b. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s)
named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
6. ☐ Application Data Sheet. See 37 CFR 1.76

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement ☒ Power of Attorney
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☒ Other: Express Mail Certificate

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP)

of prior application No. _____ / _____

Prior application information

Examiner _____

Group / Art Unit _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.**18. CORRESPONDENCE ADDRESS**☐ Customer Number or Bar Code Label

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Signature	[Signature]		Date 10/12/2000

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October 12, 2000

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Docket No. DI-5654

Inventors: RUDELL, et. al.

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MICHAEL S. LEONARD

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FEE TRANSMITTAL for FY 2000

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT (\$ 1,308.00

Complete if Known

Application Number	
Filing Date	
First Named Inventor	Scott A. Rudde11
Examiner Name	
Group Art Unit	
Attorney Docket No.	DI-5654

METHOD OF PAYMENT (check one)

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:
- Deposit Account Number 02-1444
- Deposit Account Name Baxter Int'l. Inc./Renal
- ☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17
- ☐ Applicant claims small entity status See 37 CFR 1.27
2. ☐ Payment Enclosed:
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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
101 690	201 345	Utility filing fee	690.
106 310	206 155	Design filing fee	
107 480	207 240	Plant filing fee	
108 690	208 345	Reissue filing fee	
114 150	214 75	Provisional filing fee	

SUBTOTAL (1) (\$ 690.

2. EXTRA CLAIM FEES

Total Claims	Extra Claims	Fee from below	Fee Paid
37	-20** = 17	x 18 =	306
Independent Claims 7	-3** = 4	x 78 =	312
Multiple Dependent			

**or number previously paid, if greater; For Reissues, see below

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description
103 18	203 9	Claims in excess of 20
102 78	202 39	Independent claims in excess of 3
104 260	204 130	Multiple dependent claim, if not paid
109 78	209 39	** Reissue independent claims over original patent
110 18	210 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 618.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

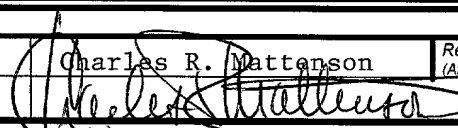
Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath	
127 50	227 25	Surcharge - late provisional filing fee or cover sheet	
139 130	139 130	Non-English specification	
147 2,520	147 2,520	For filing a request for <i>ex parte</i> reexamination	
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	
115 110	215 55	Extension for reply within first month	
116 380	216 190	Extension for reply within second month	
117 870	217 435	Extension for reply within third month	
118 1,360	218 680	Extension for reply within fourth month	
128 1,850	228 925	Extension for reply within fifth month	
119 300	219 150	Notice of Appeal	
120 300	220 150	Filing a brief in support of an appeal	
121 260	221 130	Request for oral hearing	
138 1,510	138 1,510	Petition to institute a public use proceeding	
140 110	240 55	Petition to revive - unavoidable	
141 1,210	241 605	Petition to revive - unintentional	
142 1,210	242 605	Utility issue fee (or reissue)	
143 430	243 215	Design issue fee	
144 580	244 290	Plant issue fee	
122 130	122 130	Petitions to the Commissioner	
123 50	123 50	Petitions related to provisional applications	
126 240	126 240	Submission of Information Disclosure Stmt	
581 40	581 40	Recording each patent assignment per property (times number of properties)	
146 690	246 345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149 690	249 345	For each additional invention to be examined (37 CFR § 1.129(b))	
179 690	279 345	Request for Continued Examination (RCE)	
169 900	169 900	Request for expedited examination of a design application	

Other fee (specify) _____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

Name (Print/Type)	Charles R. Mattenson	Registration No. (Attorney/Agent)	30,660	Telephone	847/948-3315
Signature		Date	10/12/2000		

Complete (if applicable)

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SPECIFICATION

TITLE:

5 **"PERITONEAL DIALYSIS CATHETERS"**

FIELD OF THE INVENTION

The present invention generally relates to catheters, and more specifically,
10 the present invention relates to dual lumen catheters having two fluid flow paths.
The catheters can be used for peritoneal dialysis to infuse and remove dialysate
simultaneously into and from a patient. The present invention also relates to
methods of implanting and using catheters.

15 **BACKGROUND OF THE INVENTION**

Kidney failure and reduced kidney function have been treated with
dialysis. Dialysis removes waste, toxins, and excess water from the body that
would otherwise have been removed by normal functioning kidneys. Dialysis
treatment for replacement of kidney functions is critical to many people because
20 the treatment is life saving. One who has failed kidneys could not continue to live
without replacing at least the filtration functions of the kidneys.

Hemodialysis and peritoneal dialysis are two types of dialysis commonly
used to treat loss of kidney function. Hemodialysis treatment utilizes the patient's

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blood to remove waste, toxins, and excess water from the patient. The patient is connected to a hemodialysis machine and the patient's blood is pumped through the machine. Catheters are inserted into the patient's veins and arteries to connect the bloodflow to and from the hemodialysis machine. The waste, toxins, and excess water are removed from the patient's blood and the blood is infused back into the patient. Hemodialysis treatment lasts several hours and is generally performed in a treatment center about three or four times per week.

Peritoneal dialysis utilizes a dialysis solution and dialysate, which is infused into a patient's peritoneal cavity. The dialysate contacts the patient's peritoneal membrane in the peritoneal cavity. Waste, toxins, and excess water pass from the patient's bloodstream through the peritoneal membrane and into the dialysate. The transfer of waste, toxins, and water from the bloodstream into the dialysate occurs due to diffusion and osmosis. The spent dialysate is drained from the patient's peritoneal cavity to remove the waste, toxins, and water from the patient and replaced.

Peritoneal dialysis catheters are used to transfer the fresh dialysate into the peritoneal cavity and remove spent dialysate from the cavity. Typically, a peritoneal catheter is implanted into the peritoneal cavity and remains implanted for an extended period of time. For example, the average catheter may remain implanted for about 18-24 months, but it is not unusual for a catheter to remain indwell for more than 2 years.

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There are various types of peritoneal dialysis, including continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis. CAPD is a manual dialysis treatment in which the patient connects the implanted catheter to a drain and allows spent dialysate fluid to drain from the peritoneal cavity. The patient then connects to a bag of fresh dialysate and manually infuses the fresh dialysate through the catheter and into the patient's peritoneal cavity. The patient disconnects the catheter from the fresh dialysate bag and allows the dialysate to dwell within the cavity to transfer waste, toxins, and excess water from the patient's bloodstream to the dialysate solution. After the dwell period, the patient repeats the manual dialysis procedure. The patient performs several drain, fill, and dwell cycles during the day, for example, about four times per day. Each treatment cycle typically takes about 3-4 hours. Manual peritoneal dialysis performed by the patient requires quite a lot of time and effort by the patient. The patient is routinely inconvenienced leaving ample opportunity for therapy enhancements to improve patient quality of life.

Automated peritoneal dialysis is similar to continuous peritoneal dialysis in that the dialysis treatment includes a drain, fill, and dwell cycle. However, a dialysis machine automatically performs 3-4 cycles of peritoneal dialysis treatment, typically overnight while the patient sleeps. A dialysis machine is fluidly connected to the implanted catheter. The dialysis machine is also fluidly connected to a source of fresh dialysate, such as a bag of dialysate solution, and to a fluid drain.

The dialysis machine pumps spent dialysate from the peritoneal cavity through the catheter to the drain. Then, the dialysis machine pumps fresh dialysate from the dialysate source through the catheter and into the patient's peritoneal cavity. The dialysis machine allows the dialysate to dwell within the cavity to transfer waste, toxins, and excess water from the patient's bloodstream to the dialysate solution. The dialysis machine is computer controlled so that the dialysis treatment occurs automatically when the patient is connected to the dialysis machine, for example, overnight. Several drain, fill, and dwell cycles will occur during the treatment. Also, a last fill is typically used at the end of the automated dialysis treatment so that the patient can disconnect from the dialysis machine and continue daily functions while dialysate remains in the peritoneal cavity. Automated peritoneal dialysis frees the patient from manually performing the drain, dwell, and fill steps, and can improve the patient's dialysis treatment and quality of life.

Various catheters exist for patient implantation to perform peritoneal dialysis. Existing peritoneal catheters include single lumen and dual lumen catheters. A single lumen catheter has a single fluid passageway through the catheter, and a dual lumen catheter has two fluid passageways. Single lumen catheters allow fluid flow in only one direction into or out of the patient at any given moment. Dual lumen catheters allow fluid flow both into and out of the patient at the same time. Because catheters are surgically implanted into patients and because the catheters allow fluids to be infused into and drained from the

patients, improvements to catheters and methods of implanting and using catheters can be beneficial.

SUMMARY OF THE INVENTION

5 The present invention provides new catheters, particularly for continuous flow peritoneal dialysis (CFPD). In CFPD, dialysate flows continuously, i.e. simultaneously, into and out of the patient. The new catheters have two lumens. One lumen allows for fresh dialysate to be infused into the patient, and the other lumen allows for spent dialysate to be removed from the patient. Accordingly, 10 fresh dialysate can flow into the patient simultaneously with spent dialysate flowing out of the patient. It is anticipated that a dialysis machine will be used to automatically perform the dialysis treatment using the new catheters.

 The new catheter delivers fresh dialysate into the peritoneal cavity at a location significantly separated from a location at which the catheter removes 15 spent dialysate from the peritoneal cavity. The separation of the patient inflow and outflow locations of the catheter tends to enhance mixing of the dialysate within the peritoneal cavity. Also, as the dialysate flows from the patient inflow location through the peritoneal cavity to the patient outflow location, the dialysate may tend to contact a relatively large area of the peritoneal membrane. A situation in 20 which the dialysate flows directly from the patient inflow location to the patient outflow location on the catheter with minimal contact of the peritoneal membrane,

shunting, tends to be avoided. At the patient inflow location, the catheter has fluid openings from the inflow lumen which are directed away from the fluid openings to the patient outflow lumen at the patient outflow location. This direction of the patient inflow fluid openings also tends to enhance dialysate mixing and minimize

5 shunting within the peritoneal cavity.

One catheter according to the present invention extends from a proximal end outside of the patient, upward into the patient and to a preformed bend. The proximal end has openings to the patient inflow and outflow lumens for connection to a dialysis machine, including a dialysate supply and drain. The patient inflow

10 lumen extends from the proximal end to a patient inflow port at the preformed bend. The catheter continues to extend downward from the preformed bend to a distal end inside of the patient's peritoneal cavity. The patient outflow lumen extends from the proximal end to a patient outflow port at the distal end. The distal end of the catheter may have a coiled shape. As implanted into the patient,

15 the preformed bend is positioned in the upper area of the peritoneal cavity and the coiled distal end is positioned in the lower area of the peritoneal cavity. CT Scan and MRI imaging of normal peritoneal dialysis patients lying in supine position (on back) with fluid filled peritoneal cavities shows two distinct pools of fluid. One pool is found in the upper region of the cavity in the vicinity of the liver and

20 spleen. The second pool is located in the lower pelvic region separated from the upper pool by the intestinal mass. This catheter shape was conceived to take

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advantage of this reality by locating the patient in flow section in the upper pool where fresh dialysate is infused directly. Once infused, the fresh dialysate is forced to filter down through the intestinal mass to the patient outflow section strategically located in the lower pool. This process enhances mixing with spent

5 dialysate and exposes a large area of the peritoneal membrane to “fresher” dialysate for improved toxin and water removal. The catheter shape also assists in maintaining the catheter position within the peritoneal cavity, i.e., the patient inflow preformed bend positioned high in the peritoneum and the patient outflow end positioned low in the peritoneum. This can help reduce or prevent omental

10 adhesion to the catheter due to catheter tip migration which causes catheter fluid flow obstructions.

During dialysis treatment, fluid can flow from the proximal end through the patient inflow lumen, out of the patient inflow port, and into the peritoneal cavity. The fluid inside the cavity contacts the peritoneal membrane, mixes with

15 fluid in the cavity, removes waste, toxins, and water, and flows to the patient outflow port at the distal catheter end. The fluid then flows from the distal end through the patient outflow lumen to the catheter proximal end and is removed from the patient.

Various advantages of the present invention can become apparent upon

20 reading this disclosure including the appended claims with reference to the accompanying drawings. The advantages may be desired, but not necessarily

required to practice the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of a catheter according to the principles of the
5 present invention.

Figure 2 is a schematic view of the catheter of Fig. 1 implanted into a
patient.

Figure 3 is an end view of an external catheter end of the catheter of Fig.
1.

10 Figure 4 is a cross-sectional view of the catheter of Fig. 1 along the line
IV-IV.

Figure 5 is a perspective view of a portion the catheter of Fig. 1 showing
fluid ports from a patient inflow lumen.

15 Figure 6 is a cross-sectional view of the catheter of Fig. 1 along the line
VI-VI.

Figure 7 is a perspective view of a portion of the catheter of Fig. 1
showing an alternate fluid port from the patient inflow lumen.

Figure 8 is a cross-sectional view along the line VI-VI of Fig. 1 showing
the alternate embodiment of Fig. 7.

20 Figure 9 is a cross-sectional view of the catheter of Fig. 1 along the line
IX-IX.

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Figure 10 is a longitudinal cross-sectional view of a portion of the catheter of Fig. 1 which transitions from a patient inflow section to a separation section.

Figure 11 is a cross-sectional view of the catheter of Fig. 1 along the line IX-IX showing an alternate cross-section.

Figure 12 is a longitudinal cross-sectional view of a portion of the catheter of Fig. 1 which transitions from a patient inflow section to a separation section according to the alternate embodiment of Fig. 11.

Figure 13 is a cross-sectional view of the catheter of Fig. 1 along the line XIII-XIII.

Figure 14 is a perspective view of a portion the catheter of Fig. 1 according to Fig. 13.

Figure 15 is a cross-sectional view along the line XIII-XIII of Fig. 1 showing an alternate fluid port to the patient outflow lumen.

Figure 16 is a perspective view of a portion of the catheter of Fig. 1 showing the alternate embodiment of the fluid port to the patient inflow lumen of Fig. 15.

Figure 17 is a cross-sectional view of the catheter of Fig. 1 along the line XIII-XIII showing an alternate cross-section.

Figure 18 is a cross-sectional view of the catheter of Fig. 1 along the line XIII-XIII showing an alternate cross-section.

Figure 19 is a cross-sectional view of the catheter of Fig. 1 along the line XIII-XIII showing an alternate cross-section.

Figure 20 is a plan view of a portion of an alternate catheter according to the principles of the present invention.

5 Figure 21 is a schematic partial cross-sectional view of a patient showing the catheter of Fig. 1 implanted in the patient.

Figure 22 is a schematic view showing the catheter of Fig. 1 being implanted into a patient.

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DETAILED DESCRIPTION OF PRESENTLY PREFERRED EMBODIMENTS

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Although the present invention can be made in many different forms, the presently preferred embodiments are described in this disclosure and shown in the attached drawings. This disclosure exemplifies the principles of the present invention and does not limit the broad aspects of the invention only to the
20 illustrated embodiments.

A new catheter 10 according to the principles of the present invention is shown by way of example in Fig. 1. The catheter 10 is implanted into a patient's peritoneal cavity for peritoneal dialysis. Referring also to Fig. 2, the catheter 10 is

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The catheter 10 is made of flexible medical grade tubing 14 suitable for

implanting inside a patient. Referring to Fig. 1, the catheter 10 can be described as having four main sections, a connection section 16, a patient inflow section 18, an inflow/outflow separation section 20, and a patient outflow section 22. The connection section 16 extends from an external catheter end 24 (proximal end) to a junction 26 with the patient inflow section 18. The patient inflow section 18 is a curved segment which extends from the junction 26 to a junction 28 with the separation section 20. The separation section 20 extends from the junction 28 with the patient inflow section 18 to a junction 30 with the patient outflow section 22. The patient outflow section 22 extends from the junction 30 to an internal catheter end 32 (distal end). The locations of the junctions 26, 28, 30 and the lengths and shapes of the sections 16, 18, 20, 22 can vary depending on the embodiment of the invention.

Referring to Figs. 1 and 2, the connection section 16 of the catheter 10 provides the function of connecting the catheter 10 to a dialysate supply and removal system, such as an automated continuous flow peritoneal dialysis system (not shown). The external catheter end 24 is positioned external to the patient 12 and is connected to the automated continuous flow peritoneal dialysis system. The catheter 10 has a generally vertical orientation when implanted into the patient 12, with the patient inflow section 18 positioned vertically upward, toward the upper area of the peritoneal cavity. The connection section 16 extends vertically downward and out of the patient 12 at an exit site 34. The separation section 20

also extends vertically downward from the patient inflow section 18. The patient outflow section 22 is positioned downward toward the bottom of the peritoneal cavity.

An end view of the external catheter end 24 is shown in Fig. 3. A patient inflow lumen 36 allows fluid to flow into the patient from a port 38 at the catheter end 24. A patient outflow lumen 40 allows fluid to flow out of the patient from a port 42 at the catheter end 24. A septum 44 separates the patient inflow and outflow lumens 36, 40 from each other. Accordingly, the patient inflow and outflow lumens 36, 40 allow simultaneous fluid flow into and out of the patient via the dual lumen catheter 10.

Referring to Figs. 1 and 2, the connection section 16 also provides for anchoring the catheter 10 to the patient. One or more implant cuffs 46, 48 on the connection section 16 anchor the catheter 10 to the patient. The implant cuffs 46, 48 can be polyester felt or other material which allows tissue ingrowth into the cuffs. The catheter 10 is implanted into the patient with the cuff 46 positioned just below the patient's skin and the cuff 48 imbedded in the patient's rectus muscle. The subcutaneous tissue grows into the implant cuffs 46, 48 to anchor the catheter 10 to the patient. When the catheter 10 is implanted inside of a patient, the portion of the catheter 10 from the external catheter end 24 close to the cuff 46 is external to the patient, and is called an external patient portion 50. The remainder of the catheter 10 is implanted inside of the patient and is called an implantable

portion 52. As shown in Fig. 1, the implantable portion 52 has a generally non-linear shape, although portions of the implantable portion 52 may be substantially linear.

A radiopaque stripe 54 extends along the length of the catheter 10 with reference to Figs. 1 and 3. Preferably, the radiopaque stripe 54 extends along the patient outflow lumen 40; however, the radiopaque stripe 54 can be located at any position on the catheter 10 as desired. Under x-ray, the radiopaque stripe 54 shows the position of the catheter 10 inside of the patient.

Fig. 4 shows the connection section 16 in cross-section along the section line IV-IV in Fig. 1. The cross-section of the connection section 16 (Fig. 4) is generally consistent along the length of the connection section 16 from the external catheter end 24 to the junction 26. Except, the cuffs 46, 48 are not shown in Fig. 4. Also, the cross-section in the area of the junction 26 may change as the connection section 16 transitions to the patient inflow section 18, depending on the cross-section of the patient inflow section 18.

Referring to Figs. 1 and 5, the patient inflow section 18 has a fluid opening (port) 56 to the patient inflow lumen 36 to allow dialysate to exit the patient inflow lumen 36 and be infused into the peritoneal cavity. The patient inflow section 18 is preformed to a curved shape to form a curved segment. Preferably, the fluid opening 56 is a plurality of round holes through the catheter tube wall along the outer radial surface of the curved inflow segment 18. The

5 downward.

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tortuous path to reach the patient outflow section 22. This tends to enhance dialysate contact on the peritoneal membrane and improve mixing. Improved dialysate contact with the peritoneal membrane and better mixing can improve the dialysis treatment of the patient.

5 The patient inflow section 18 has been described as having a curved shape. The term curved contemplates structures other than a smooth curve of the tube 14, e.g. a non-linear shape. If one follows along the catheter 10 from the proximal end 24 upward, the patient inflow section 18 reverses the longitudinal direction of the catheter 10 to a downward direction to reach the distal end 32. In
10 addition to having the fluid openings 56, the patient inflow section 18 connects connection section 16 and the separation section 20 together. Accordingly, the curved term contemplates many different shapes, such as an inverted U, an inverted V, a straighter line with right angles at the ends of the lines, and any other structure to connect the connection section 16 to the separation section 20. Also,
15 the patient inflow section 18 is preformed as a curved segment and generally retains its curved shape. Although the tube 14 is flexible, the form-retentive tube 14 will tend to retain its curved shape of the patient inflow section 18 when implanted inside of the patient. The entire tube 14 of the catheter 10 has the flexible, form-retentive characteristic.

20 An alternative patient inflow section 58 is shown in Figs. 7 and 8. Instead of the round holes for the fluid opening 56 in the patient inflow section 18 (Figs. 5

and 6), the patient inflow section 58 has elongated slots 60 to allow dialysate to flow into the peritoneal cavity. Also, the patient inflow lumen is two patient inflow lumens 62 separated by a septum 64. The septum 64 can have openings to allow fluid flow between both patient inflow lumens 62. The fluid opening 56 can have shapes other than round holes and slots, as desired, for example, elongated holes.

Referring to Fig. 1, the implantable portion 52 of the catheter 10 has a separation section 20. The separation section 20 is a generally straight section of the flexible tube 14 which separates the patient inflow section 18 and the patient outflow section 20 from each other. As described above, when the catheter 10 is implanted into a patient, the patient inflow section 18 is generally positioned at an upper area of the peritoneal cavity to deliver dialysate to the patient. The separation section 20 positions patient outflow section 22 downward toward the lower area of the peritoneal cavity and away from the patient inflow section 18.

The separation section 20 allows dialysate flowing into the patient at the patient inflow section 18 to travel a great distance in the peritoneal cavity to reach the patient outflow section 22. The great distance of dialysate fluid flow in the peritoneal cavity also tends to improve the dialysis therapy because the dialysate can contact a greater portion (surface area) of the peritoneal membrane and improved mixing of fresh and spent dialysate can occur.

Fig. 9 shows a cross-section of the separation section 20 from the

junction 28 with the patient inflow section 18 to the junction 30 with the patient outflow section 22. In this embodiment, the separation section 20 has the patient outflow lumen 40 without the patient inflow lumen 36 because the patient inflow lumen 36 has been terminated. Fig. 10 shows a longitudinal cross-section of the catheter 10 in the area of the junction 28 between the patient inflow section 18 and the separation section 20. The patient inflow lumen 36 terminates at an end 66. The catheter 10 transitions from a dual lumen catheter to a single lumen catheter.

Figs. 11 and 12 show cross-sections of an alternative separation section 68. In this embodiment, separation section 68 has both a patient inflow lumen 70 and a patient outflow lumen 72. A septum 74 separates the patient inflow and outflow lumens 70, 72. In this embodiment, the patient inflow lumen 70 may terminate and be closed at or before the distal catheter end 32.

The patient outflow section 22 is shown in Fig. 1. The patient outflow section 22 has a preformed, coiled shape. A fluid opening (port) 76 and the open distal end 32 are open to the patient outflow lumen 40 to allow fluid to exit the peritoneal cavity through the catheter 10. Referring also to Figs. 13 and 14, the fluid opening is preferably a plurality of holes 76 generally all around the exterior of the tube 14 from the junction 30 to the distal end 32. The patient outflow section 22 with the fluid opening 76 is spaced a great distance from the patient inflow section 18 and the fluid opening 56. Accordingly, dialysate fluid must flow from the patient inflow section 18 - positioned in the upper area of the peritoneal

cavity – a great distance to the patient outflow section 22 – positioned in the lower area of the peritoneal cavity. The inflow and outflow of dialysate fluid through the catheter 10 can occur simultaneously.

Figs. 15 and 16 show an alternative patient outflow section 78. In this
5 embodiment, instead of holes 76, the fluid opening is a plurality of elongated slots 80. Several septums 82 are connected together and hold the outer tube portions 84 together. The patient outflow lumen is partitioned into several patient outflow lumens 86 by the septums 82. The septums 82 can have openings to allow fluid flow between any of the patient outflow lumens 86. Of course, the fluid opening
10 76 in the patient outflow section could have shapes other than holes and slots as desired.

Figs. 17-19 show additional alternate cross-sections of the patient outflow section 22. In Fig. 17, the patient outflow section 88 has slots 80 on only the side of the tube having the radiopaque stripe 54. Lumen 90 can be part of the
15 patient outflow lumen by carrying fluid out of the patient from an open distal end 32 and/or from fluid openings through the septums 82 to the lumens 86. The lumen 90 could be part of the patient inflow lumen 36, but would have a closed end at or prior to the distal end 32. The patient outflow section 88 of Fig. 17 may have greater structural strength around lumen 90 because there are no slots
20 opposite the radiopaque stripe 54. Accordingly, the lumen 90 may provide greater containment of a stiffening stylet inserted into the lumen 90 during implantation of

the catheter 10. The patient outflow section 92 of Fig. 18 is similar to the patient outflow section 88 of Fig. 17. Except, the slots 80 in the Fig. 18 embodiment are on the side of the tube opposite the radiopaque stripe. The patient outflow section 94 of Fig. 19 is similar to the patient outflow section 88 of Fig. 17. Except, holes 76 replace the slots 80.

Fig. 20 shows an alternative embodiment of the catheter 10. In this embodiment, the catheter 10 is generally the same as previously described embodiments, except for the patient outflow section 22. The flexible patient outflow section 96 has a substantially straight shape rather than the coiled shape of the patient outflow section 22 shown in Fig. 1. The patient outflow section 96 has a port, such as a plurality of holes 76 or slots 80, for the patient outflow lumen 40. The cross-sections of the patient outflow sections shown in Figs. 13, 15, and 17-19 are also applicable to the patient outflow section 96 of Fig. 20.

Implantation of the catheter 10 into a patient will now be described. Generally, the catheter 10 can be implanted by accepted catheter implantation methods, including open surgical dissection, peritoneoscopic, and percutaneous, for example, with modifications due to the new catheters of the present invention. Because the open surgical dissection method is the most commonly used implantation method for existing peritoneal dialysis catheters, an open surgical dissection implantation method for the catheter 10 will be described. This disclosure of the invention is not a medical text and, thus, the procedural steps

described below do not constitute a complete formal medical procedure. Medical professionals should determine and apply all appropriate procedures.

I. Patient Preparation

5 Preparation for catheter placement should follow accepted hospital procedures for general abdominal surgery.

1. Empty the patient's bowel and bladder. An enema should be used, if necessary.

2. Shave the insertion area and mark entrance and exit locations
10 with a sterile ink pen. Referring to Fig. 21, the entrance site 98 will be located approximately 3 – 6 cm directly above the exit site 100, or above and slightly to the side of the exit site 100. These locations of the entrance and exit sites 98, 100 provide for the external patient portion 50 of the catheter 10 to be directed downward and the implantable portion 52 to point upward to the patient inflow
15 section 18.

3. Prepare the sterile field. After a Betadine scrub, the entrance and exit markings may need to be reapplied.

4. Anesthetize the area locally where the initial incision, tunnel and subsequent skin puncture will be made. Avoid general anesthesia whenever
20 possible.

5. Patient is now ready for implantation of the catheter 10.

II. Catheter Implantation

1. A 3 - 4 cm transverse incision 102 is made through the skin 104 and subcutaneous tissue 106. The transverse incision 102 is continued down
5 through the anterior rectus sheath 108.
2. The rectus muscle fibers 110 are separated to expose the posterior rectus sheath 112.
3. An incision is made through the posterior rectus sheath 112, transversalis fascia 114, and parietal peritoneum 116 no larger than necessary to
10 introduce the catheter 10.
4. A purse-string suture 117 is placed around the incision to help seal after catheter insertion.
5. The catheter 10 is placed in a sterile saline bath while compressing the cuffs 46, 48 to remove any entrapped air.
- 15 6. Referring to Figs. 21 and 22, a stiffening stylet 118 is inserted into the patient outflow lumen 40 (lumen identified by radiopaque stripe) of the catheter 10. The stylet 118 stiffens the catheter 10 and straightens the curved patient inflow section 18 and the coiled patient outflow section 22 for easier insertion. The stylet 118 should fall at least 1 cm short of the distal end 32 of the
20 catheter 10 to prevent perforation of the bowel 120 or other intraperitoneal injury.

7. As shown in Fig. 22, the catheter 10 is initially directed downward toward the lower pelvis with the stylet 118 pointing downward. With the coiled patient outflow section 22 embodiment, once the catheter tip (distal end 32) is deep in the pelvic cavity the stylet 118 is slowly removed approximately 20 cm while simultaneously advancing the catheter 10 deeper to allow the coil to reform its coiled shape and remain low in the pelvis.

8. Once the catheter tip (distal end 32), coiled or straight embodiments, is properly located low in the pelvis, the stylet 118 removed another 10 cm while advancing the catheter 10 inward by the same amount. At this point the stylet 118 should remain fixed while advancing the catheter 10 all the way into the peritoneum 122 until the distal cuff 48 is seated firmly in the rectus muscle 110 but not protruding into the peritoneum 122.

9. The portion of the stylet 118 and catheter 10 external to the patient is rotated approximately 135° downward with the portion of the stylet 118 and catheter 10 inside of the patient rotated upward as shown in Fig. 22 to force the patient inflow section 18 into the upper portion of the abdomen near the liver. During this step the catheter 10 should be kept as close to the abdominal wall as possible. Ideal placement would result in the catheter 10 lying in the area between the intestinal mass (bowels 120) and the posterior abdominal wall as shown in Fig.

20 21.

10. The purse-string suture 117 is firmly cinched around the

catheter 10. An additional suture can be added to secure the cuff 48 to the rectus muscle 110 if desired.

III. Subcutaneous Tunnel

- 5 1. A tunneling tool is inserted into one of the catheter lumens 36, 40.
2. A small scalpel puncture is made at the premarked exit site 100 location which is directly below or below and slightly to one side of the entrance site 98 location.
- 10 3. Referring to Fig. 21, the tunneling tool with catheter 10 attached is advanced from the original entrance site incision 102, under the skin 104 and out the scalpel puncture at the exit site 100 forming a straight, stress-free subcutaneous tunnel. The catheter 10 is pulled through the tunnel until the catheter 10 is straightened and the proximal cuff 46 is approximately 2 cm below 15 the skin surface.

IV. Finish Procedure

1. An adapter is attached to the proximal end 24 of the catheter 10 and catheter flow is assessed by infusing and draining saline solution 20 through both lumens 36, 40.
2. Once the fluid flow function is validated, the entrance site incision 102 is closed. Suturing of exit site 100 is not recommended.

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3. The catheter 10 is secured to the skin and the exit wound is dressed appropriately.

Dialysis may begin as early as required, but recommended no sooner than 2 weeks.

5 The catheter 10 and the implantation method provides for an unstressed, straight tunnel through the patient's tissue into the peritoneal cavity 122. Also, the exit site 100 is directed downward so the external patient portion 50 of the catheter 10 is positioned in a downward direction. The catheter 10 can have a close implant cuff spacing (small distance between implant cuffs 46, 48).

10 Accordingly, only a small length of catheter tubing between the implant cuffs 46, 48 will be positioned within the patient's abdominal wall tissue.

While the presently preferred embodiments have been illustrated and described, numerous changes and modifications can be made without significantly departing from the spirit and scope of this invention. Therefore, the inventors
15 intend that such changes and modifications are covered by the appended claims.

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THE INVENTION IS CLAIMED AS:

- 1 1. A dialysis catheter comprising:
2 a tube having an implantable portion extending from an external patient
3 portion, the implantable portion having a curved segment between the external
4 patient portion and a distal end of the implantable portion;
5 a first lumen extending through the tube from a first lumen port in the
6 external patient portion to a first lumen port in the curved segment of the
7 implantable portion; and
8 a second lumen extending through the tube from a second lumen port in
9 the external patient portion to a second lumen port in the implantable portion, the
10 second lumen port in the implantable portion being spaced away from the first
11 lumen port in the curved segment.
- 1 2. The dialysis catheter of claim 1, further comprising at least
2 one implant cuff on the implantable portion of the tube.
- 1 3. The dialysis catheter of claim 1, wherein the first lumen port
2 in the curved segment comprises a plurality of openings at an outer radial surface
3 of the curved segment.
- 1 4. The dialysis catheter of claim 3, wherein the plurality of
2 openings are substantially round holes.
- 1 5. The dialysis catheter of claim 3, wherein the plurality of
2 openings are slots.

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1 16. A dialysis catheter comprising:

2 a connection section having an inflow port to a patient inflow lumen, and
3 an outflow port to a patient outflow lumen;

4 a patient inflow section extending from the connection section and having
5 a patient inflow opening to the patient inflow lumen;

6 a separation section extending from the patient inflow section; and

7 a patient outflow section extending from the separation section and
8 having a patient outflow opening to the patient outflow lumen.

1 17. The dialysis catheter of claim 16, wherein when the catheter
2 is in a substantially unstressed condition, the connection section is substantially
3 straight, the patient inflow section is curved, and the separation section is
4 substantially straight.

1 18. The dialysis catheter of claim 17, wherein the patient outflow
2 section is coiled.

1 19. The dialysis catheter of claim 17 wherein the patient outflow
2 section is substantially straight.

1 20. The dialysis catheter of claim 16, wherein the patient inflow
2 section is an uppermost portion of an implantable portion of the catheter and the
3 patient outflow section is a lowermost portion of the implantable portion of the
4 catheter.

1 21. The dialysis catheter of claim 16, wherein the connection
2 section, patient inflow section, separation section, and patient outflow section

3 further comprise a flexible tube having an internal septum between the patient
4 inflow and outflow lumens.

1 22. The dialysis catheter of claim 16, wherein the patient inflow
2 section has a curved shape.

1 23. The dialysis catheter of claim 16, wherein the patient inflow
2 opening to the patient inflow lumen is in a direction away from the patient outflow
3 opening to the patient outflow lumen.

1 24. The dialysis catheter of claim 16, wherein the catheter
2 comprises a single tube having the patient inflow and outflow lumens, and wherein
3 the tube transitions from having both the patient inflow and outflow lumens to
4 having only the patient outflow lumen at a location between the patient inflow
5 section and a distal catheter end.

1 25. A peritoneal dialysis catheter comprising a flexible single tube
2 having first and second lumens, the first lumen extending from a first fluid opening
3 to a second fluid opening, the second lumen extending from a third fluid opening
4 to a fourth fluid opening, the first and third fluid openings being in an external
5 patient portion of the catheter, the second and fourth fluid openings being in an
6 implantable portion of the catheter and spaced apart from each other, the
7 implantable portion of the catheter have an generally non-linear shape.

1 26. The peritoneal dialysis catheter of claim 25, wherein the
2 second fluid opening is located at a non-linear shaped section of the implantable

1 31. The dialysis catheter of claim 29, wherein the patient outflow
2 section has a coiled shape.

17 flowing fluid into a first lumen at a proximal end of the catheter;
18 flowing the fluid in the first lumen to a curved path of the first lumen;
19 flowing the fluid in the curved path through a fluid opening in the curved

1 path and out of the catheter;

2 flowing the fluid which exited the catheter from the opening in the curved

3 path into a second lumen at a distal end of the catheter; and

4 flowing the fluid in the second lumen to a fluid opening at the proximal

5 end of the catheter and out of the catheter.

1 37. A method of implanting a catheter into a patient comprising

2 the steps of:

3 straightening the catheter with a stylet inside of the catheter;

4 inserting a distal end of the straightened catheter through an entrance

5 incision into a peritoneal cavity of the patient while directing the straightened

6 catheter downward;

7 removing part of the stylet from the catheter while advancing the catheter

8 into the peritoneal cavity until the distal end is located in a lower area of the

9 peritoneal cavity and a distal implant cuff is seated in a rectus muscle of the

10 patient;

11 rotating a portion of the stylet and catheter outside of the patient

12 downward and a portion of the stylet and catheter inside of the patient upward;

13 and

14 pulling the catheter through a subcutaneous tunnel having an exit site

15 below the entrance incision.

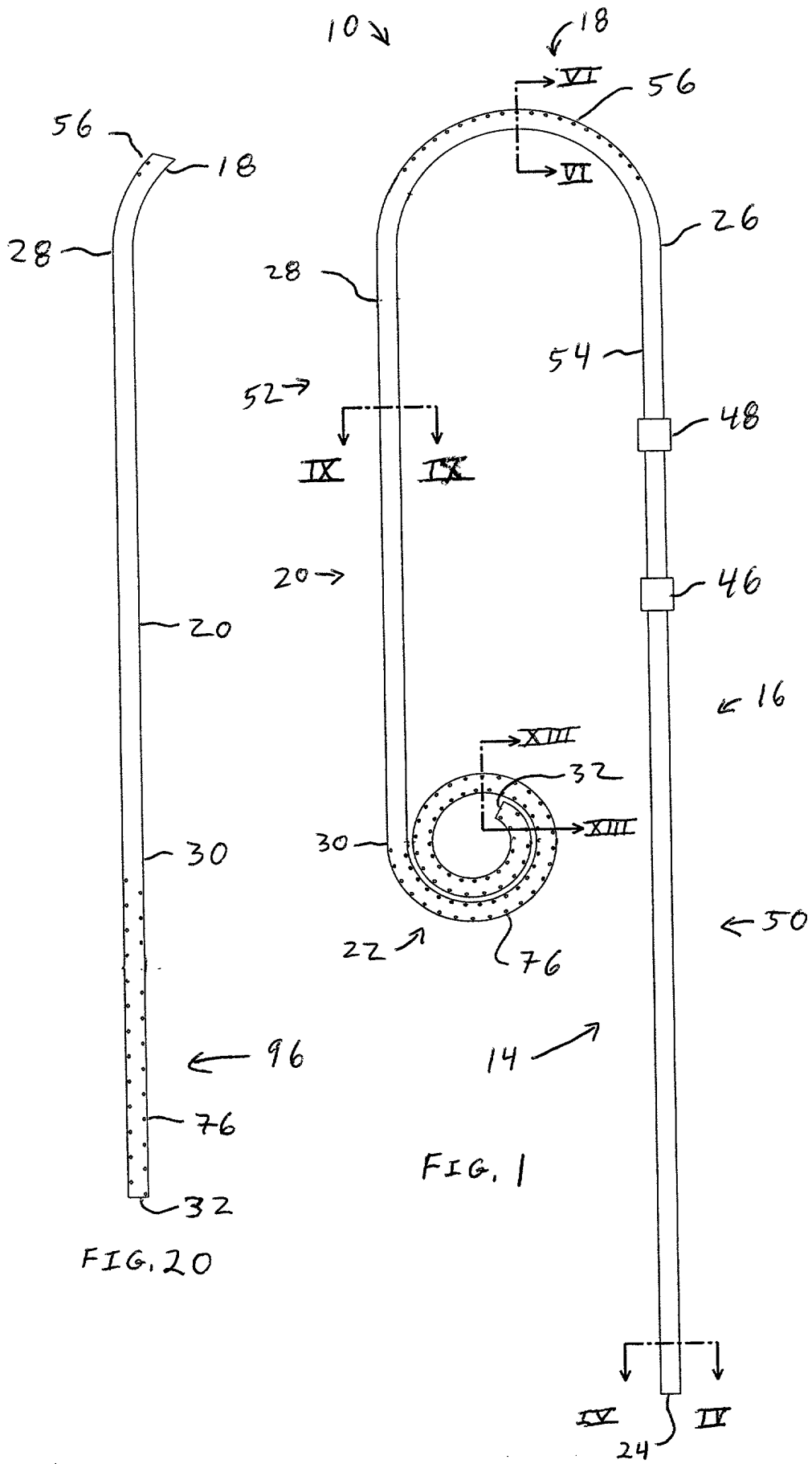
ABSTRACT

A catheter suitable for use in performing peritoneal dialysis. The catheter is a dual lumen catheter which allows for continuous flow peritoneal dialysis.

Dialysate flows through the catheter into the patient via one lumen and
5 simultaneously flows through the catheter out of the patient via the second lumen.

The dual lumen dialysis catheter has a flexible tube which has an implantable portion extending from an external patient portion. Both of the lumens have openings in the external patient portion for connecting to a supply and drain of dialysate, respectively. The implantable portion has a preformed curved segment
10 which has an outlet for the first lumen to flow dialysate into the patient's peritoneal cavity. The implantable portion has an opening for the second lumen at the distal end to flow dialysate out of the peritoneal cavity and removal from the patient. The catheter facilitates mixing of fresh and spent dialysate inside the peritoneal cavity by inflowing fresh dialysate into the cavity at a location
15 substantially separated from the cavity outflow location, and by directing the inflow of dialysate into the cavity opposite the cavity outflow location.

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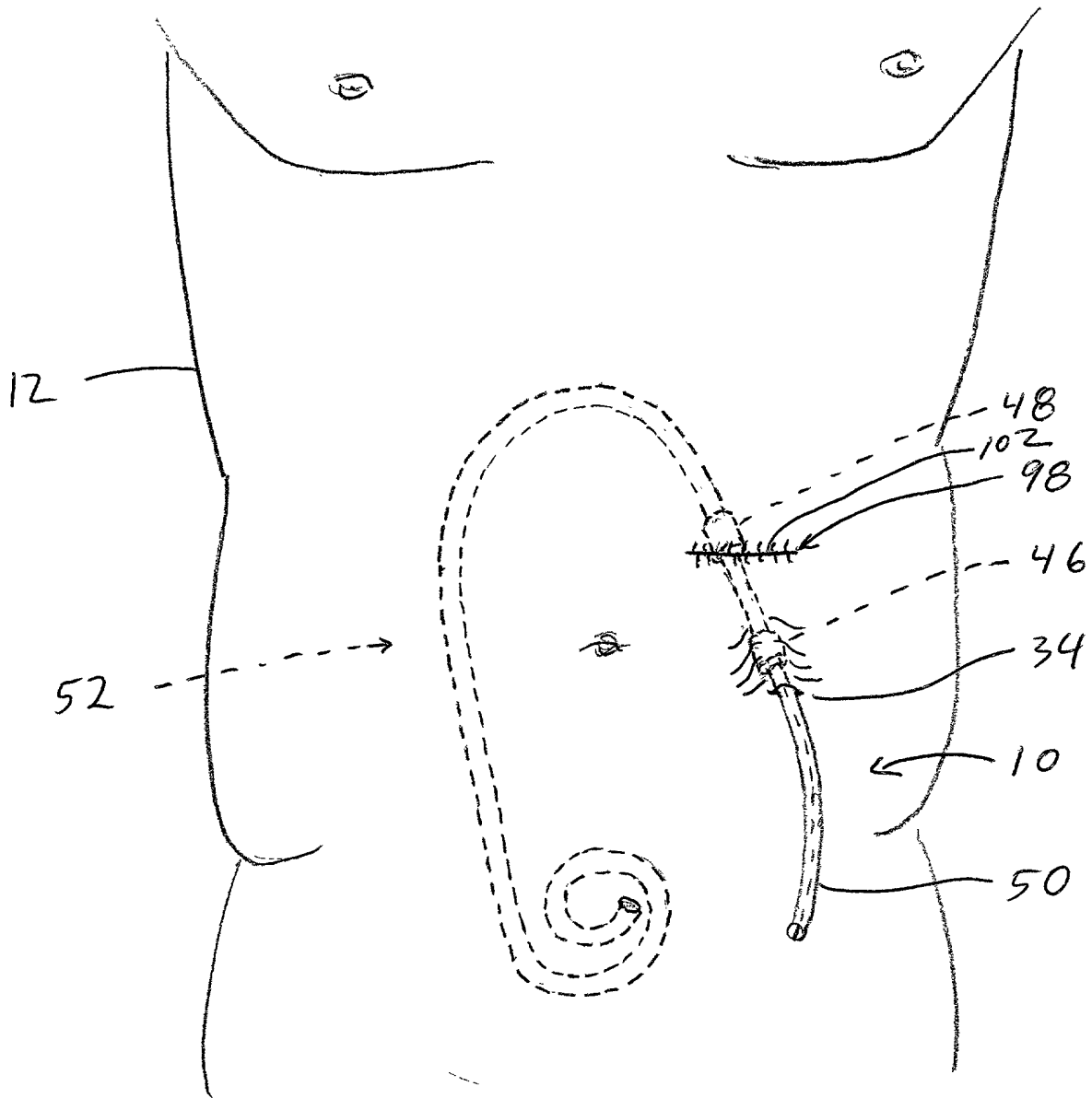


FIG. 2

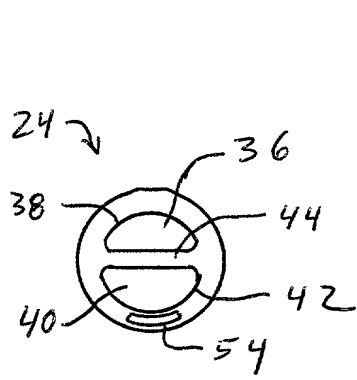


FIG. 3

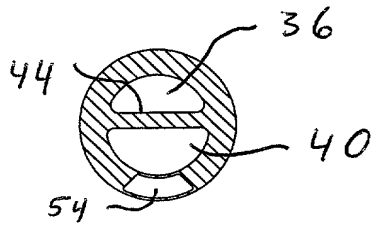


FIG. 4

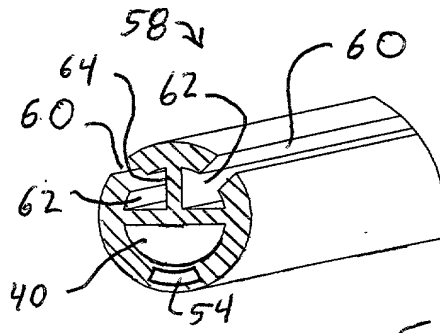


FIG. 7

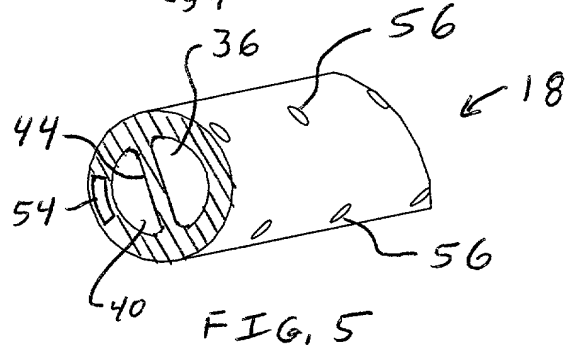


FIG. 5

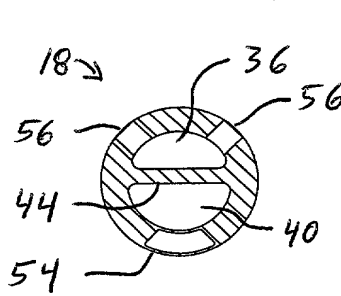


FIG. 6

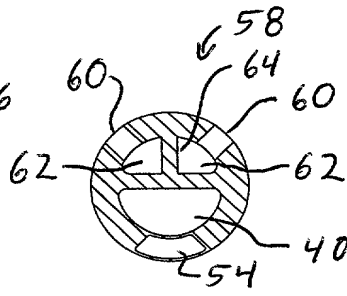


FIG. 8

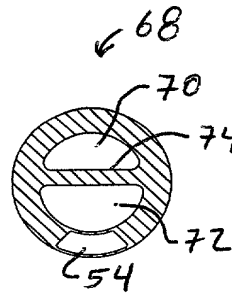


FIG. 11

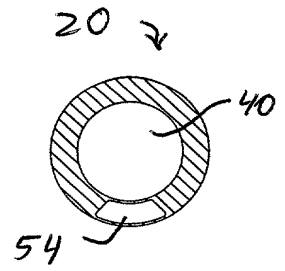


FIG. 9

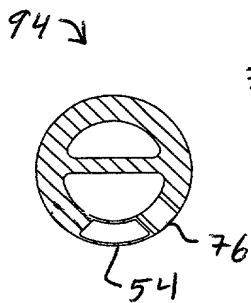


FIG. 19

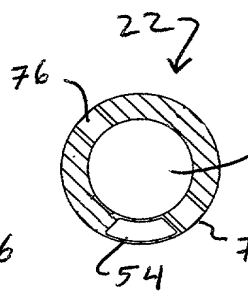


FIG. 13

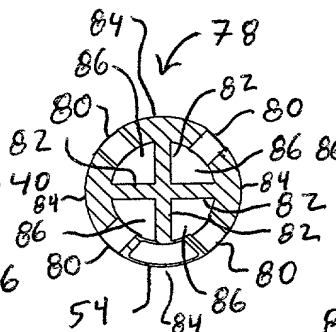


FIG. 15

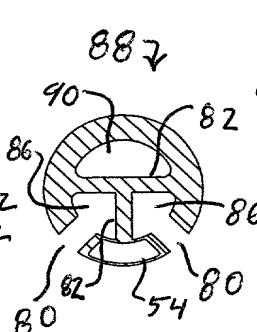


FIG. 17

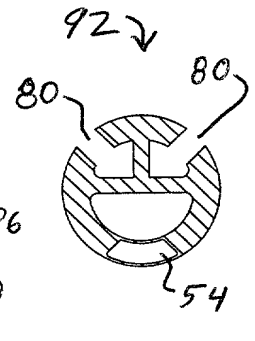


FIG. 18

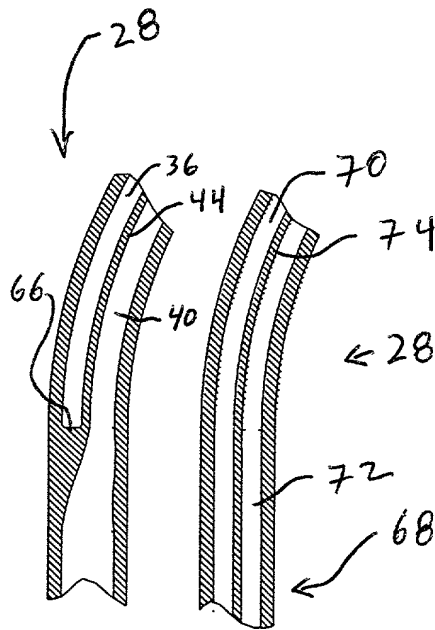
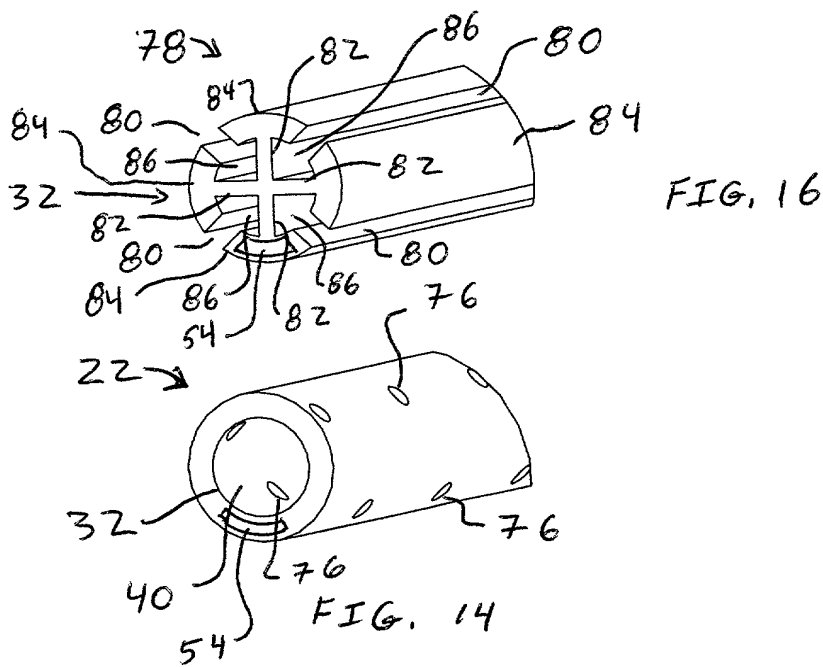
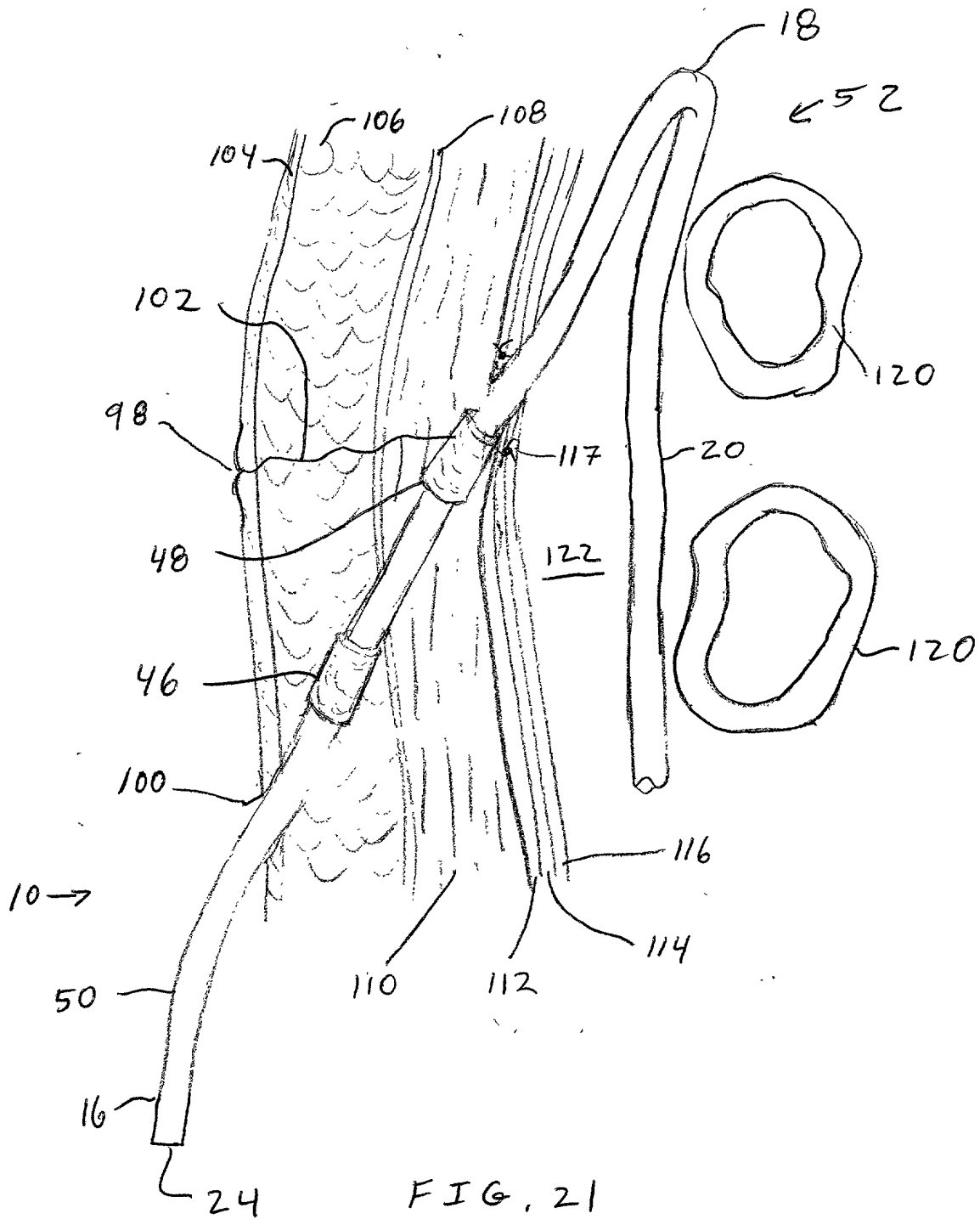


FIG. 10 FIG. 12





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Docket No. DI-5654

Page 1 of 2

COMBINED DECLARATION AND POWER OF ATTORNEY
IN ORIGINAL APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name;

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: "Peritoneal Dialysis Catheters"

the specification of which; (check one)

☒ [X] is attached hereto.☐ [] was filed on _____ as Application
Serial Number _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)Priority Claimed

N/A _____
(Number) (Country) (Day/Month/Year Filed) [] []

(Number) (Country) (Day/Month/Year Filed) [] []

(Number) (Country) (Day/Month/Year Filed) [] []

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Residence	Citizenship	
Post Office Address		


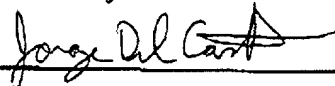
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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